

AMENDED IN SENATE MAY 5, 1998

SENATE BILL

No. 1800

Introduced by Senator Johnston

February 18, 1998

An act to amend Sections 124975 and 124980 of, *and to amend and renumber Section 125005 of*, the Health and Safety Code, relating to hereditary disorders, *and making an appropriation therefor*.

LEGISLATIVE COUNSEL'S DIGEST

SB 1800, as amended, Johnston. Hereditary disorders.

(1) Existing law requires the Director of Health Services to establish any regulations and standards for hereditary disorders programs as the director deems necessary to promote and protect the public health and safety in accordance with certain principles.

This bill would require that the standards for hereditary disorders include approval, accreditation, certification, or licensure of personnel offering screening programs for hereditary disorders.

(2) Existing law provides that among the principles for the establishment of any regulations and standards for hereditary disorders is that counseling services for these disorders be available through the program or a referral source for all persons determined to be or who believe themselves to be at risk for a hereditary disorder when the belief arises as a result of screening programs.

This bill would require, for purposes of these regulations and standards, that pre- and post-counseling services for

hereditary disorders be provided by persons with appropriate training and experience. The bill would also revise certain legislative findings and declarations relating to hereditary disorders.

(3) *Existing law requires the State Department of Health Services to charge a fee for testing of newborns for genetic disease, and requires the department to deposit these moneys in the Genetic Disease Testing Fund, a special fund, that is continuously appropriated to the department for purposes of carrying out provisions relating to genetic disease testing of newborns. Existing law also contains provisions relating to hereditary disorders, sickle cell anemia, and prenatal testing for genetic disorders and birth defects.*

This bill would authorize the department to charge a fee for any activities, services, and programs carried out pursuant to provisions relating to hereditary disorders, sickle cell anemia, and prenatal testing for genetic disorders and birth defects, and would require that these fees be deposited in the Genetic Disease Testing Fund to be used by the department for these activities, services, and programs. By increasing the amount of moneys in a continuously appropriated fund, and by expanding the purposes for which these continuously appropriated funds may be used, this bill would make an appropriation.

Vote: majority. Appropriation: ~~no~~ yes. Fiscal committee: yes. State-mandated local program: no.

The people of the State of California do enact as follows:

1 SECTION 1. Section 124975 of the Health and Safety
2 Code is amended to read:

3 124975. The Legislature hereby finds and declares
4 that:

5 (a) Each person in the State of California is entitled to
6 health care commensurate with his or her health care
7 needs, and to protection from inadequate health services
8 not in the person's best interests.

9 (b) Hereditary disorders, such as sickle cell anemia,
10 cystic fibrosis, and hemophilia, are often costly, tragic,



1 and sometimes deadly burdens to the health and
2 well-being of the citizens of this state.

3 (c) Detection through screening of hereditary
4 disorders can lead to the alleviation of the disability of
5 some hereditary disorders and contribute to the further
6 understanding and accumulation of medical knowledge
7 about hereditary disorders that may lead to their eventual
8 alleviation or cure.

9 (d) There are different severities of hereditary
10 disorders, that some hereditary disorders have little effect
11 on the normal functioning of individuals, and that some
12 hereditary disorders may be wholly or partially alleviated
13 through medical intervention and treatment.

14 (e) All or most persons are carriers of some deleterious
15 recessive genes that may be transmitted through the
16 hereditary process, and that the health of carriers of
17 hereditary disorders is substantially unaffected by that
18 fact.

19 (f) Carriers of deleterious genes should not be
20 stigmatized and should not be discriminated against by
21 any person within the State of California.

22 (g) Specific legislation designed to alleviate the
23 problems associated with specific hereditary disorders
24 may tend to be inflexible in the face of rapidly expanding
25 medical knowledge, underscoring the need for flexible
26 approaches to coping with genetic problems.

27 (h) State policy regarding hereditary disorders should
28 be made with full public knowledge, in light of expert
29 opinion and should be constantly reviewed to consider
30 changing medical knowledge and ensure full public
31 protection.

32 (i) The extremely personal decision to bear children
33 should remain the free choice and responsibility of the
34 individual, and should not be restricted by the state.

35 (j) Participation of persons in hereditary disorders
36 programs in the State of California should be wholly
37 voluntary, except for initial screening for
38 phenylketonuria (PKU) and other genetic disorders
39 treatable through the California newborn screening
40 program. All information obtained from persons involved

1 in hereditary disorders programs in the state should be
2 held strictly confidential.

3 (k) In order to minimize the possibility for abuse of
4 genetic intervention in hereditary disorders in the state,
5 all screening programs for heredity disorders shall
6 comply with the principles established in the Hereditary
7 Disorders Act (Section 27). The Legislature finds it
8 necessary to establish a uniform statewide policy for the
9 screening for heredity disorder in the State of California.

10 SEC. 2. Section 124980 of the Health and Safety Code
11 is amended to read:

12 124980. The director shall establish any regulations
13 and standards for hereditary disorders programs as the
14 director deems necessary to promote and protect the
15 public health and safety. Standards shall include
16 approval, accreditation, certification, or licensure of
17 personnel offering screening programs for hereditary
18 disorders. Regulations adopted shall be in accordance
19 with the principles established pursuant to this section.
20 These principles shall include, but not be limited to, the
21 following:

22 (a) The public, especially communities and groups
23 particularly affected by programs on hereditary
24 disorders, should be consulted before any regulations and
25 standards are adopted by the department.

26 (b) The incidence, severity and treatment costs of
27 each hereditary disorder and its perceived burden by the
28 affected community should be considered; and that
29 where appropriate, state and national experts in the
30 medical, psychological, ethical, social, and economic
31 effects or programs for the detection and management of
32 hereditary disorders should be consulted by the
33 department.

34 (c) Information on the operation of all programs on
35 hereditary disorders within the state, except for
36 confidential information obtained from participants in
37 the programs, shall be open and freely available to the
38 public.

39 (d) Clinical testing procedures and protocols
40 established for use in programs, facilities, and projects

1 should be accurate, and provide maximum information,
2 and produce results that are subject to minimum
3 misinterpretation.

4 (e) No test or tests shall be performed on any minor
5 over the objection of the minor's parents or guardian, nor
6 may any tests be performed unless the parent or guardian
7 is fully informed of the purposes of testing for hereditary
8 disorders, and is given reasonable opportunity to object
9 to the testing.

10 (f) No testing, except initial screening for PKU and
11 other diseases that may be added to the newborn
12 screening program, shall require mandatory
13 participation, and no testing programs shall require
14 restriction of childbearing, and participation in a testing
15 program shall not be a prerequisite to eligibility for, or
16 receipt of, any other service or assistance from, or to
17 participate in, any other program, except where
18 necessary to determine eligibility for further programs of
19 diagnoses of or therapy for hereditary conditions.

20 (g) Pre- and post-counseling services for hereditary
21 disorders shall be available, through the program or a
22 referral source, for all persons determined to be or who
23 believe themselves to be at risk for a hereditary disorder
24 when the belief arises as a result of screening programs.
25 Counseling shall be provided by persons with appropriate
26 training and experience and shall be nondirective, and
27 emphasize informing the client.

28 (h) All participants in programs on hereditary
29 disorders be protected from undue physical and mental
30 harm, and except for initial screening for PKU and other
31 diseases that may be added to newborn screening
32 programs, be informed of the nature of risks involved in
33 participation in the programs, and those determined to
34 be affected with genetic disease be informed of the
35 nature, and where possible, the cost of available therapies
36 or maintenance programs, and be informed of the
37 possible benefits and risks associated with ~~such~~ *these*
38 therapies and programs.

39 (i) All testing results and personal information
40 generated from hereditary disorders programs shall be

1 made available to an individual 18 years of age or over, or,
2 if under 18 years of age, to the individual's parent or
3 guardian. If the individual is a minor or incompetent, all
4 testing results that have positively determined the
5 individual to either have, or be a carrier of, a heredity
6 disorder shall be given to an appropriately trained health
7 care professional.

8 (j) All testing results and personal information from
9 hereditary disorders programs obtained from any
10 individual, or from specimens from any individual, shall
11 be held confidential and be considered a confidential
12 medical record except for any information that the
13 individual, parent, or guardian consents to be released;
14 provided that the individual is first fully informed of the
15 scope of the information requested to be released, of all
16 of the risks, benefits, and purposes for the release, and of
17 the identity of those to whom the information will be
18 released or made available, except for statistical data
19 compiled without reference to the identity of any
20 individual, and except for research purposes, provided
21 that pursuant to 45 Code of Federal Regulations Section
22 46.101 et seq. entitled "Protection of Human Subjects,"
23 the research has first been reviewed and approved by an
24 institutional review board that certifies the approval to
25 the custodian of the information and further certifies that
26 in its judgment the information is of such potentially
27 substantial public health value that modification of the
28 requirement for legally effective prior informed consent
29 of the individual is ethically justifiable.

30 (k) An individual whose confidentiality has been
31 breached as a result of any violation of the Hereditary
32 Disorders Act (Section 27) may recover compensatory
33 damages, and in addition, may recover civil damages not
34 to exceed ten thousand dollars (\$10,000), reasonable
35 attorney's fees, and the costs of litigation.

36 *SEC. 3. Section 125005 of the Health and Safety Code*
37 *is amended and renumbered to read:*

38 ~~125005.—~~

39 *124996.* The Genetic Disease Testing Fund is
40 continued in existence as a special fund in the State

1 Treasury. *The department may charge a fee for any*
2 *activities, services, and programs carried out pursuant to*
3 *this chapter.* All moneys collected by the department
4 ~~under Section 125000~~ *for activities, services, and*
5 *programs carried out pursuant to this chapter* shall be
6 deposited in the Genetic Disease Testing Fund, that is
7 continuously appropriated to the department to carry out
8 the purposes of ~~Section 125000~~ *this chapter.*

9 It is the intent of the Legislature that the ~~program~~
10 *activities, services, and programs* carried out pursuant to
11 ~~Section 125000~~ *this chapter* be fully supported from fees
12 collected for ~~such testing~~ *these activities, services, and*
13 *programs.*

